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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,839	11/01/2005	Wen-Cherng Lee	223255/121026	1086

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HONIGMAN MILLER SCHWARTZ & COHN LLP  
444 WEST MICHIGAN AVENUE  
KALAMAZOO, MI 49007-3714

EXAMINER
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KWON, BRIAN YONG S

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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03/30/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/526,839	<b>Applicant(s)</b> LEE ET AL.	
	<b>Examiner</b> Brian-Yong S. Kwon	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 30-54 is/are pending in the application.
- 4a) Of the above claim(s) 36-45, 52 and 54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 30, 32, 34, 46-51 and 53 is/are rejected.
- 7) ☒ Claim(s) 31, 33, 35 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. The examiner for the instant application has changed. The current examiner assigned to this application is Brian-Yong S. Kwon. Claims 1, 30-35 and 46-54 are presented for prosecution on the merits.

#### ***Status of Application***

2. Acknowledgement is made of applicant's amendment/remarks filed on 12/09/2008. By the amendment, claim 1 has been amended; claims 2-29 have been cancelled; and claims 46-54 have been newly added.

3. Applicant's arguments have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of actions being applied to the instant application.

4. The applicant's elected species, 4-92-(6-methyl-pyridin-2-yl)-pyrazolol[1,5-a]pyridine-3-yl]-pyrimidin-2-ylamine, appears to be allowable over the prior art. Thus, the examiner will extend the search to other non-elected species represented by the formula I (where X1, X2, X3 and X4 is CR<sup>x</sup>; Y1 and Y2 is N; R1 is halo (i.e., fluoro); R2 is alkylsulfanyl (i.e., methylsulfanyl); m =1; n=1; methylsulfanyl); R<sup>x</sup> is hydrogen) and examine for prosecution on the merits of the case. Claims 1, 30, 32, 34, 46, 47, 48, 49, 50, 51 and 53 read on the elected species. Claims 36-45, 52 and 54 are withdrawn from further consideration by examiner as being drawn to non-elected invention.

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***Claim Objections***

5. Claims 31, 33 and 35 are objected, as being improperly depending on cancelled claim 29. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Accordingly, the claim 35 has not been further treated on the merits.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 30, 32, 34, 46, 47, 48, 49, 50, 51 and 53 are rejected under 35 U.S.C. 102(e) as being anticipated by Gudmundsson et al. (US 7199120B2).

Gudmundsson discloses pyrazolo-pyridine derivatives represented by the formula (I) including Example 14 that is useful for the prophylaxis or treatment of viral infections, wherein said compound is prepared in various dosage forms and administered to human in the range of 0.02-5000mg per day, preferably 100-1500 mg per day (abstract; column 18, line 56 through column 22, line 58).

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With respect to the property of said compound in “inhibiting the TGF $\beta$  signaling pathway” or “inhibiting the TGF $\beta$  type I receptor in cell”, such property or characteristic deems to be inherent to the referenced method. The prior art directing administration of same compound in overlapping dosage amount (see page 27, lines 11-17 of the instant specification) inherently possessing therapeutic effect for the same ultimate purpose as disclosed by applicant anticipates the claimed invention even absent explicit recitation of underlying mechanism.

The American Heritage Dictionary (Second College Edition, 1982) defines the term “inhibit” as “restrain or hold back; prevent” and “prevent” as “anticipate or counter in advance, to keep from happening”. To the extent that the claims 1, 30, 32, 34, 46, 47, 48, 49, 50, 51 and 53 encompass methods of preventing the TGF $\beta$  signaling pathway or TGF $\beta$  type I receptor, the instant claims 8, 10, 12-14 and 23 are construed to read on any method of administering the claimed compounds to a subject as. In other words, the analysis of the instant claims 1, 30, 32, 34, 46, 47, 48, 49, 50, 51 and 53 allows for the inclusion of any patient population, as long as the same compound is administered to body of the patient in overlapping dosage amounts.

Applicant’s attention is directed to Ex parte Novitski 126 USPQ 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a haec verba recitation for such prophylactic utility. In the instant case, as in Ex parte Novitski, the claims are directed to preventing a malady or disease with old and well known compounds of compositions. The prior art administering compounds inherently possessing a protective utility anticipates claims directed to such protective use.

### Conclusion

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7. No Claim is allowed.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see <http://pair-direct.uspto.gov> Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

/Brian-Yong S Kwon/  
Primary Examiner, Art Unit 1614